

ORIGINAL ARTICLE

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Evaluation of the Lactate Pro blood lactate analyser

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Abstract An evaluation of the hand-held portable Lactate Pro Analyser (KDK) was undertaken to assess its accuracy, reliability and versatility. Capillary blood samples were drawn from elite athletes in both laboratory and field settings and analysed in parallel. Accuracy was determined in relation to three other lactate analysers: (1) the ABL 700 Series Acid-Base analyser ($n = 172$ cases), (2) the Accusport Lactate Meter ($n = 118$ cases), and (3) the YSI 2300 Stat lactate analyser ($n = 22$ cases). The level of agreement was determined over the range of 1–18 mM. The repeatability of results between two different Lactate Pro analysers was also determined over the same range. Versatility was assessed in the field, where the Lactate Pro was used with elite athletes under a range of outdoor and indoor testing conditions. The correlations between the Lactate Pro and the ABL 700 Series Acid-Base analyser, YSI 2300 and Accusport were $r = 0.98$, $r = 0.99$, $r = 0.97$. The correlation between the two Lactate Pro analysers on the same sample ($n = 96$ cases) was $r = 0.99$. The level of agreement between the Lactate Pro and other analysers was generally less than ± 2.0 mM over the physiological range of 1.0–18.0 mM (range of mean difference: -0.06 mM to 0.52 mM). The Lactate Pro was easy to operate and successfully completed the sample analysis in 100% of the tests performed. In summary, the Lactate Pro is accurate, reliable and exhibits a high degree of agreement with other lactate analysers.

Key words Lactate · Lactate analysis · Reliability · Accuracy · Level of agreement

Introduction

The measurement of blood lactate to assess and monitor exercise performance is a common practice in sports physiology laboratories worldwide. Lactate analysis is performed for the prescription of training velocities (Madsen and Lohberg 1987; Prins 1988; Weltman 1993), to evaluate longitudinal changes in aerobic and anaerobic fitness (Sharp et al. 1984), and to evaluate individual responses to specific training sessions (Pyne 1989). Most of the prescriptive work is directed towards determination of the anaerobic threshold and estimation of the relative anaerobic contribution to exercise from lactate formation. Research has demonstrated a strong correlation between endurance performance and the anaerobic threshold determined from lactate profiling (Coyle 1995; Pfitzinger and Freedson 1998).

Athlete testing is often required in both laboratory and field settings. Irrespective of the location, the use of blood lactate measurements is dependent upon instrumentation that is accurate, linear and reliable. The ABL 700 Series Acid-Base analyser used in our laboratory is typical of large laboratory-based analysers that provide measurements of blood lactate, glucose, pH, bicarbonate and blood gas concentrations. The two most commonly used automated analysers in sports science laboratories are the Yellow Spring Instruments (YSI) 2300 Stat analyser and the Accusport Lactate Meter (Boehringer Mannheim). For widespread use in the laboratory and field, lactate analysers need to be portable, battery operated, capable of operating under a wide range of environmental conditions, and able to process samples accurately, simply and quickly. Recently, the Lactate Pro, a portable hand-held whole-blood lactate analyser has been released. The most direct competitor for the Lactate Pro analyser is the Accusport Lactate Meter: both instruments are hand-held devices that take 60 s to

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measure the lactate concentration from a drop of blood placed on a reagent strip.

Both the Accusport (Clough et al. 1997; Fell et al. 1998; Wigglesworth et al. 1996) and Lactate Pro (Makita 1997) analysers have been evaluated in preliminary laboratory-based reports. Given the potential limitations of using correlational analysis alone, we combined this with the level of agreement statistical approach (Atkinson and Nevill 1998) to compare different analysers. The purpose of this investigation was to evaluate the suitability of the Lactate Pro for testing athletes in the field and to assess its accuracy against other laboratory and portable lactate analysers.

Methods

Subjects

Male and female athletes aged between 16 and 30 years were recruited from a number of sporting teams in training at the Australian Institute of Sport in Canberra, Australia, and an Australian Swimming National Team Camp in Darwin, Australia. Subjects signed Athlete Agreement documents, in accordance with the policies of the Australian Institute of Sport and, where appropriate, Australian Swimming Incorporated. Experimental procedures were approved by the Ethics Committee of the Australian Institute of Sport.

Experimental design

The accuracy of the Lactate Pro was determined in relation to two laboratory-based lactate analysers: the ABL 700 Series and the YSI 2300 Stat analysers, and one portable hand-held analyser, the Accusport Lactate Meter. For the purpose of this investigation, the ABL 700 Series was considered to be the criterion instrument. The laboratory participates in an external quality assurance program (QAP; Australian RCPA-AACB Chemical Pathology Quality Assurance Program, Flinders Medical Centre, South Australia) for blood glucose and lactate measurement with the ABL 700. The level of agreement between analysers was made over the range of 1–18 mM. Comparison between two different Lactate Pro analysers (Lactate Pro I and II) was made over the same range. Versatility was assessed in the field, where the Lactate Pro was used under a range of outdoor (18–30 °C) and indoor (18–22 °C) testing conditions with elite athletes. These temperatures are within the manufacturer's prescribed operating range for both the Lactate Pro (10–40 °C) and the Accusport (10–30 °C) machines.

The capillary blood samples necessary for comparison of the analysers were drawn from the following sporting groups:

1. Lactate Pro vs ABL 700, $n = 172$ cases, swimmers.
2. Lactate Pro vs YSI 2300, $n = 22$ cases, cyclists.
3. Lactate Pro vs Accusport, $n = 118$ cases, swimmers.
4. Lactate Pro I v Lactate Pro II, $n = 96$ cases, swimmers.

Exercise protocols

Blood lactate samples were taken in the laboratory from the cyclists during and after a progressive incremental cycle ergometer test to exhaustion. Samples taken from swimmers and analysed by the ABL 700 and Lactate Pro analysers were obtained during and after a 7 × 200-m progressive incremental swimming test. Samples for the comparison of the Lactate Pro and Accusport Lactate Meter were taken from swimmers after routine interval-training sets. All

capillary blood samples were taken within 30 s of the completion of each swim.

Lactate analysers

The Lactate Pro has recently been released by Akray (KDK) of Japan. It is a hand-held portable analyser capable of measuring whole-blood lactate in the field. A small blood sample size of only 5 µl is required. The reagent strip fills by capillary action directly from the earlobe or fingertip site. Lactate in the sample reacts with potassium ferricyanide and lactate oxidase to form potassium ferrocyanide and pyruvate. Upon the application of a given voltage, ferrocyanide is oxidised, releasing electrons and creating a current. This current is measured amperometrically and is directly proportional to the lactate concentration of the blood sample. The Lactate Pro is supplied with a Check Strip (to confirm that the analyser is operating correctly) and a Calibration Strip that provides a non-quantitative indication of instrument accuracy.

The Radiometer ABL 700 (Radiometer Copenhagen, Denmark) is a blood gas analyser that incorporates Co-oximetry, electrolyte and metabolite measurement. This analyser is designed for laboratory use only and is not portable or suitable for fieldwork. Lactate measurement by the ABL 700 requires a 75-µl capillary blood sample. Blood lactate passes across the outer layer of a multi-layered membrane and reacts with lactate oxidase that has been immobilised between the layers, to form pyruvate and H₂O₂. The H₂O₂ passes across the inner membrane, where it is subjected to a given potential and oxidised, creating a current that is measured amperometrically. The size of the current is directly proportional to the lactate concentration of the sample.

The ABL 700 was routinely calibrated every 4 h, according to the manufacturer's recommendations. Two of the four levels of control materials were analysed daily. The ABL 700 met all QAP performance standards for proportional bias, precision and linearity in lactate measurement during the study period. Three levels of quality control material (Bio Rad) were analysed three times during the day.

The Accusport Lactate Meter (Boehringer Mannheim) is a portable hand-held analyser that requires between 10 and 25 µl of blood, employs a dry-chemistry methodology and displays the result in 1 min. The sample is applied to a reagent strip where lactate is converted to pyruvate and molybdenum blue via lactate oxidase. The molybdenum blue, which is proportional to the lactate concentration, is measured by reflectance photometry. The Accusport was calibrated regularly at the beginning of each day and after every 20 samples, with proprietary standards of known concentration (range 1.7–3.1 mM, and 4.5–7.0 mM).

The YSI 2300 Stat (Yellow Springs Instruments, Ohio, USA) is a laboratory-based analyser that measures both lactate and glucose from a 25-µl capillary blood sample. A platinum electrode is used to detect the production of H₂O₂ from oxidation of the substrate. The H₂O₂ is in turn oxidised, with the resulting electron flow being linearly proportional to the steady-state H₂O₂, and therefore, to the concentration of the substrate (lactate). In contrast to the other three analysers, which employed a non-haemolysed whole-blood method, the blood samples for YSI analysis were haemolysed (YSI 1515 Lysing Agent) and stabilised (YSI 2357 Buffer) before analysis. The YSI 2300 was calibrated regularly at the beginning of each day and after every 15 samples, with quality controls of known concentration [1.5 (0.2) and 7.5 (0.3) mM].

All analysers were cleaned, calibrated and operated in accordance with the manufacturer's instructions. Blood samples were drawn from either the finger tip or earlobe of the swimmer or cyclist, with the site standardised for a given athlete. Variation in sampling site is known to elicit different blood lactate concentrations (Foxdal et al. 1990, 1991). All samples were analysed within 60 s of collection.

Statistical analysis

Comparison of analysers was achieved with Pearson product-moment correlation analysis, standard linear regression and the level of agreement. While correlation analysis indicates the degree to which two variables are associated, it does not necessarily indicate the extent to which values agree or disagree. To overcome this limitation, the approach of quantifying the level of agreement between two different lactate analysers measuring the same parameter (in this case blood lactate concentration) was employed (Atkinson and Nevill 1998). The mean difference between analysers (± 2 standard deviations or 95% of a normally distributed population) was determined. Inspection of the slope and intercept of the linear regression was also undertaken to characterise the level of agreement between analysers.

Results

The results for each analyser comparison are presented in two graphical formats. Firstly, each comparison is illustrated by correlational analysis, which shows the linear regression equation, the correlation coefficient and the 95% confidence intervals (Fig. 1: Lactate Pro vs ABL 700 Series Acid-Base analyser; Lactate Pro I vs Lactate Pro II; Lactate Pro vs Accusport Lactate Meter; Lactate Pro vs YSI 2300 Stat). Secondly, the level of

agreement (± 2 standard deviations) between the Lactate Pro and each of the other analysers is shown in Fig. 2 (Lactate Pro vs ABL 700 Series Acid-Base analyser; Lactate Pro I vs Lactate Pro II; Lactate Pro vs Accusport Lactate Meter; Lactate Pro vs YSI 2300 Stat).

The correlations between the Lactate Pro and the ABL 700 Series Acid-Base analyser, YSI 2300 and Accusport were $r = 0.98$, $r = 0.99$ and $r = 0.97$, respectively. The correlation between two different Lactate Pro analysers in analysing the same blood sample was $r = 0.99$. The agreement between each pair of analysers under analysis was generally less than ± 2.0 mM over the range of 1.0–18.0 mM (Table 1). The Lactate Pro successfully completed the sample analysis on 100% of the tests performed. Although the YSI 2300 analyser uses a haemolysed blood sample for lactate determination, the comparative results with this analyser were similar to those obtained with the ABL 700 and Accusport.

The slope and intercept of the linear regression plots indicate the degree of agreement between the Lactate Pro and each of the other three analysers. The slope values in comparison with the Lactate Pro were 1.008, 1.192 and 1.062 for the ABL 700 Series Acid-Base Analyser, Accusport and YSI 2300 Stat, respectively (Fig. 1). Essentially, these results indicate that the values provided by the Lactate Pro are in good agreement with those provided by both the ABL 700 Series Acid-Base and the YSI 2300 analysers. However, the level of

Fig. 1 Correlation plots ($\pm 95\%$ confidence interval) between the Lactate Pro analyser (*Lactate Pro I*) and the ABL 700 Series Acid-Base analyser, Accusport Lactate Meter, YSI 2300 Stat Lactate Analyser, and a second Lactate Pro analyser (*Lactate Pro II*)

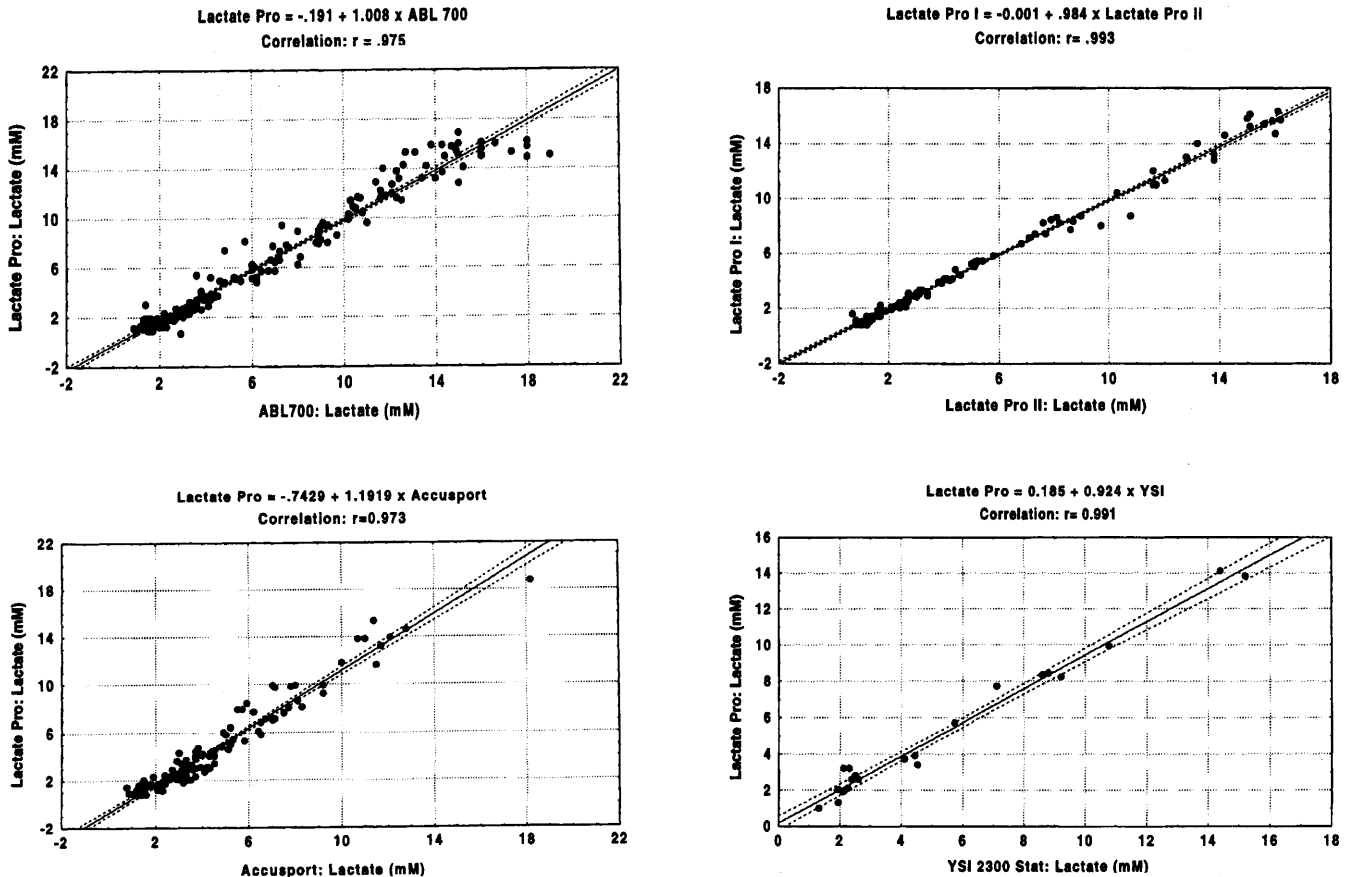


Fig. 2 Level of agreement (Bland Altman) plots showing linear regression analysis (mean difference ± 2 standard deviations) between the Lactate Pro analyser (*Lactate Pro I*) and the ABL 700 Series Acid-Base analyser, Accusport Lactate Meter, YSI 2300 Stat lactate analyser, and a second Lactate Pro analyser (*Lactate Pro II*)

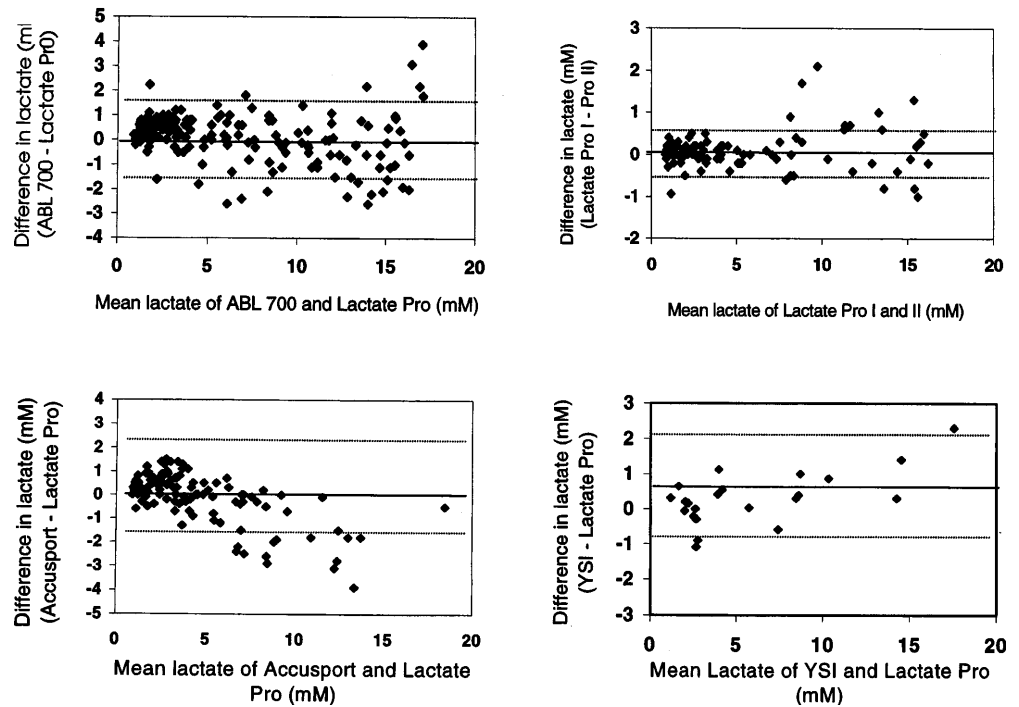


Table 1 Comparison of the Lactate Pro analyser with three other lactate analysers and a second Lactate Pro analyser (*Lactate Pro II*), showing the mean difference and the range of mean differences between each pair. (2SD Two standard deviations)

Lactate Pro analyser compared with	Mean difference (mM)	Standard deviation (mM)	Range of mean difference ($\pm 2SD$) (mM)
ABL 700	0.13	0.98	(-1.83 to 2.09)
YSI 2300	0.52	0.75	(-0.98 to 2.02)
Accusport	-0.06	1.04	(-2.14 to 2.02)
Lactate Pro II	0.08	0.30	(-0.52 to 0.68)

agreement with the Accusport Lactate Meter deteriorates at lactate values higher than 8.0 mM (Fig. 2). Above this level, there is clear evidence that the Accusport reads lower than the Lactate Pro. For example, at a Lactate Pro reading of 10.0 mM the Accusport read only 9.0 mM, and when the Lactate Pro read 16.0 mM the Accusport read only 14.0 mM.

Discussion

The results obtained in this evaluation support the use of the Lactate Pro as an accurate and reliable lactate analyser in the field. The strong correlations ($r > 0.96$) between the Lactate Pro and existing analysers (ABL 700 Series Acid-Base analyser, YSI 2300 Stat analyser and Accusport Lactate Meter) and the limits of agreement of less than 2.0 mM through the physiological range of 1.0–18.0 mM underline the suitability of the Lactate Pro. These results support the preliminary findings of Makita (1997), who also demonstrated a strong relationship

($r = 0.99$) against the Accusport ($n = 313$ cases).

The lactate values obtained in this evaluation were generally less than 18.0 mM, and consequently the statistical treatment of the data is only applicable to that limit. This evaluation has not addressed the issue of linearity beyond the 18.0 mM lactate concentration that may occur in some sports such as sprint running and track cycling. However, in most sports blood lactate levels do not often exceed this level (Lowensteyn et al. 1994; Telford et al. 1988), and the Lactate Pro is therefore suitable for the majority of field applications across a wide range of sports. Future studies may address the specific instances where blood lactate values exceed 18.0 mM.

The “limits of agreement” analysis (Altman and Bland 1983) was introduced as a measure of absolute reliability, to overcome some of the limitations associated with the standard error of the mean (SEM) and coefficient of variation (CV). The results of this preliminary evaluation show that the results produced by the Lactate Pro appear to be homoscedastic (i.e. there appears to be no obvious relationship between the degree of disparity between analysers and level of lactate measured). This is in contrast to the Accusport Lactate Meter, which exhibits a degree of heteroscedasticity, where values in excess of 8 mM appear to be substantially lower than in other analysers, and this difference increases with increasing levels of blood lactate concentration.

The Lactate Pro requires a sample size of only 5 μ l and does not require any pipetting of blood on to the reagent strip. This eliminates the potential for experimental error related to pipetting, and facilitates a more

rapid measurement. Initial indications are that the Lactate Pro can analyse a sample and display the result approximately 30 s more quickly than the Accusport. Both the Accusport and Lactate Pro were highly reliable in completing blood lactate analysis, although the test strip with the Accusport occasionally needed to be inserted two or three times before being accepted. Handling the protective foil cover surrounding the reagent strip with the Lactate Pro takes some practice, but is eventually quite straightforward.

In summary, this evaluation has shown that the Lactate Pro exhibits a high degree of accuracy with other lactate analysers, good reliability and a high degree of versatility under a variety of testing conditions.

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